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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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ROSETTA-GENOMICS c/o PSWS 700 W. 47TH STREET SUITE 1000 KANSAS CITY, MO 64112			EXAMINER SHIN, DANA H	
			ART UNIT 1635	PAPER NUMBER
			MAIL DATE 09/16/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/536,560	Applicant(s) BENTWICH, ITZHAK	
	Examiner DANA SHIN	Art Unit 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 February 2008 and 18 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-51 is/are pending in the application.
- 4a) Of the above claim(s) 35-49 and 51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-34 and 50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2-26-08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 26, 2008 has been entered.

Election/Restrictions

Applicant's election with traverse of claims 21-34 pertaining to SEQ ID NO:2079 in the reply filed on August 18, 2008 is acknowledged. The traversal is on the ground(s) that claims 50 and 51 depend from claims 21 and 35 which have unity of invention and therefore claims 50 and 51 also have unity of invention. This is not found persuasive because the independent claim, claim 21, does not have a special technical feature that contributes over prior art as evidenced by the prior art rejections applied in the instant case, and therefore, the instant application lacks unity of invention.

The requirement is still deemed proper and is therefore made FINAL.

Status of Claims

Currently, claims 21-51 are pending. Claims 35-49, 51, and SEQ ID NOs:1-2078, 2080-3353 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to

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nonelected inventions, there being no allowable generic or linking claim. Accordingly, claims 21-34 and 50 pertaining to SEQ ID NO:2079 are under examination on the merits.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on February 26, 2008 is being considered by the examiner, except citation No. C7: "BARTON NH, et al., Evolution. 2007; inside cover. Cold Spring Harbor Laboratory Press, Cold Spring Harbor, NY.", because the copy (having a web address http://home.planet.nl/~gkorthof/images/tree_of_life2/jpg) submitted for this citation does not correspond to the name of the citation. Further, even if the provided copy corresponds to the NPL citation, the copy is not legible. Thus, it is not considered.

Response to Arguments

Applicant's arguments and the declaration under 37 C.F.R. §1.132 filed on February 26, 2008 with respect to the 103(a) rejections for claims 21-49 addressing the previous final Office action have been considered but are moot in view of the new ground(s) of rejection. See below.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) or 121 as follows:

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The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

None of the disclosure of the prior-filed applications provides adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application, because none discloses the claimed molecule structure, let alone SEQ ID NO:2079. Hence, the earliest effective filing date for claims 21-34 and 50 will be the filing date of PCT/IL03/00998, filed on November 26, 2003. If applicant believes that any of the prior-filed applications provide adequate support for claims 21-34 and 50, applicant is required to provide particulars in response to this Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-34 and 50 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the

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relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims require “17 to 24 nucleotides” for the first nucleotide and “50 to 131 nucleotides” for the second nucleotide, loop segments of 3 to 19 nucleotides, “72.7%” or “44.1%” complementarity, “-11.3 Kcal/mol” for a negative free energy, and SEQ ID NO:2079.

Applicant’s arguments filed on February 26, 2008 with regard to claims 21-34 are fully considered but they are not persuasive. Applicant argues that since specific SEQ ID NOs meet either the upper limit or the lower limit of the claimed length parameters and the complementarity and the negative free energy values, the specification complies with the written description requirement. In so doing, applicant states that SEQ ID NO:2458 is “17 nucleotides in length”; SEQ ID NO:644 is “131 nucleotides in length”; SEQ ID NO:57 has a stem that is “44.1%” complementary, whose free energy value is “-11.3 Kcal/mol”; and SEQ ID NO:2964 has “at least 72.7%” complementarity. Applicant further argues that the specification satisfies the written description requirement because one can use statistical analyses or mathematical calculations. For example, applicant states that analyses of 1593 disclosed hairpins show that 98.1% of the hairpin loops range from 3-19 nucleotides with a SD of 3.2 nucleotides and that one can obtain a free energy of -11.3 Kcal/mol by simply calculating the stem-loop structure of SEQ ID NO:57. As such, applicant has arbitrarily picked and chose a specific sequence to show support for a certain claim limitation.

First, applicant’s attention is directed to *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 56 USPQ2d 1486 (Fed. Cir. 2000), wherein the Court expressed the following while citing *In re Rushig*, 379 F.2d 990, 154 USPQ118 (CCPA 1967): “As *Ruschig* makes clear, one

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cannot disclose a forest the original application, and then later pick a tree out of the forest and say “here is my invention.” In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure.”

In the instant case, the specification discloses 424,571 nucleotide sequences and applicant alleges that the application discloses “1797 viral miRNAs”. See page 24 of the remarks.

As such, there is nothing in the written disclosure of the instant application as originally filed that directs a skilled artisan to a specific parameters of “17 to 24 nucleotides” and “50 to 131 nucleotides” and specific numerical values of “72.7%” or “44.1%” and the specific SEQ ID NO:2079 out of a total of 424,571 disclosed nucleotide sequences or a total of “1797 viral miRNAs”. Further, there is nothing that leads to a skilled artisan to the critical and particular claim limitations (length, complementarity, free energy, nucleotide sequence) from the forest of 424,571 disclosed nucleotide sequences or a total of “1797 viral miRNAs”, let alone to obtain such limitations by employing statistical and mathematical tools, which require checking all “1797 viral miRNAs” disclosed in the instant application.

Even if one had the means and time and effort to undergo the statistical and mathematical analyses of the entire “1797 viral miRNAs” disclosed in the instant application, nothing in the specification as originally filed suggests that one should pick the specific length parameter of “17 to 24 nucleotides”, “50 to 131 nucleotides”, and “3 to 19 nucleotides” or the claimed “72.7%” or “44.1%” complementarity, or the claimed value of “-11.3 Kcal/mol” for a negative free energy, or the claimed SEQ ID NO:2079. That is, the instant specification as originally filed does not provide any blaze marks directing a skilled artisan to a specific tree (in the instant case, all the recited structural requirements).

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In view of the foregoing, it is concluded that the specification fails to comply with the written description requirement under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21-22, 25, and 33-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Zamore et al. (US 2006/0009402 A1).

The claims are drawn to an isolated nucleic acid, wherein the nucleic acid is a mature sequence that is part of an miRNA precursor comprising the sequence of the mature miRNA and a hairpin sequence and the mature miRNA binds and inhibits mRNA transcribed from a viral genome.

Zamore et al. teach isolated miRNA precursors (about 100 nucleotides or longer in length, for example 72 nucleotides (see SEQ ID NO:1)), which comprise two stem portions (about 18-19 or 22 or 25 nucleotides in length) that are partially complementary and are connected by a hairpin loop portion (about 3 or 15 or 20 nucleotides in length). They teach that the stem portions comprise a mature miRNA, which binds and targets a portion of the mRNA of

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a target gene and inhibits translation of the mRNA, thereby inhibiting the expression of the mRNA. They teach that the target gene of the miRNA is a viral gene or viral genes. They teach that one can express miRNA precursors or miRNAs by incorporating them into an vector. See paragraphs 0006-0009, 0041-0043; claims 1-41, 55-56. Since the isolated miRNA precursors of Zamore et al. meet the structural limitations set forth in the claims, the claims are anticipated by Zamore et al.

Claims 21-22, 25, and 33-34 are rejected under 35 U.S.C. 102(e) as being anticipated by Cullen et al. (US 2004/0053411 A1).

The claims are described above.

Cullen et al. teach isolated nucleic acids that encode miRNA precursors that comprise mature miRNAs, which induce degradation of the mRNA transcript of a target gene sequence or inhibit the translation of the mRNA, wherein the target gene includes viral RNA. They teach that mature miRNAs are about 19-24 nucleotides in length and complementary to the target sequence within the mRNA. They teach that isolated miRNAs can be designed to target the 3'-UTR or the 5'-UTR of the mRNA. They teach that miRNA precursors are 40-100 nucleotides or preferably 50-75 nucleotides in length, which includes a loop sequence of 6-15 nucleotides in length. They teach vectors comprising miRNA precursors. See paragraphs 0019-0025, 0029; claim 27. Since the isolated miRNA precursors of Cullen et al. meet the structural limitations set forth in the claims, the claims are anticipated by Cullen et al.

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Claims 21-22, 33-34, and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Khvorova et al. (US 2007/0031844 A1).

The claims are drawn to a first nucleic acid that is 17-24 nucleotides in length and at least 72.7% complementary to a target mRNA, wherein the first nucleic acid sequence is SEQ ID NO:2079.

Khvorova et al. teach a nucleic acid that is 19 nucleotides in length and at least 72.7% identical to the nucleotide sequence of SEQ ID NO:2079. See SEQ ID NO:1360090 and below for sequence alignment. They also teach that the nucleic acid can be inserted into a vector. They teach that one can use SEQ ID NO:1360090 to inhibit target mRNA. See paragraph 0266.

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Qy          2  GGAAGGACGGGAAGUGGAA 20
              | | | | | | | | | | | | | |
Db          1  GCAAGGAAGGGAAGUGGAA 19

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Since the nucleic acid of Khvorova et al. meets the structural requirements set forth in the claims, the claims are anticipated by Khvorova et al.

Claims 21-22, 33, and 50 are rejected under 35 U.S.C. 102(e) as being anticipated by Buxton et al. (WO 2004/053157 A2).

The claims are described above.

Buxton et al. teach a nucleic acid of SEQ ID NO:89 that is 18 nucleotides in length and at least 72.7% identical to SEQ ID NO:2079. See below for sequence alignment. They teach that SEQ ID NO:89 can be used as a probe for screening assays or can be used to inhibit target gene expression. See the entire reference including Table 2.

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Qy          1  UGGAAGGACGGGAAGU 16
              : | | | | | | | | | | :
Db          2  TGGAAAGGCGGGAAAGT 17

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Since the nucleic acid of Buxton et al. meets the structural requirements set forth in the claims, the claims are anticipated by Buxton et al.

Claims 21-22, 33, and 50 are rejected under 35 U.S.C. 102(b) as being anticipated by Stacey et al. (WO 00/31540).

The claims are described above.

Stacey et al. teach a nucleic acid of SEQ ID NO:10 that is 20 nucleotides in length and at least 72.7% identical to SEQ ID NO:2079. See below for sequence alignment. They teach that SEQ ID NO:10 oligonucleotide can be used to inhibit target mRNA. See pages 28.

Qy	3	GAAGGACGGGAAGUGGAAGU	22
		: :	
Db	1	G TAGGACCGGAAGTGGGAGT	20

Since the nucleic acid of Stacey et al. meets the structural requirements set forth in the claims, the claims are anticipated by Stacey et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 21-34 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ambros (*Cell*, 2001, 107:823-826) in view of Lai et al. (*Genome Biology*, 2003, 4:R42) and Knipe et al. (*PNAS*, 1979, 76:4534-4538).

The claims are drawn to an isolated nucleic acid wherein the nucleic acid is a 22-nucleotide miRNA of SEQ ID NO:2079, which is part of a miRNA precursor comprising the sequence of and a hairpin sequence.

The instant specification teaches that the claimed invention is "bioinformatically" identified by using "bioinformatic gene detection engine" and that the claimed invention is identified from a viral genome. See pages 4 and 15.

Ambros teaches that miRNAs are evolutionarily widespread and that "many more miRNAs will be identified" in other organisms than worms, flies, and humans by structure-based informatics searches of noncoding genomic sequences. See page 824. Ambros does not teach an miRNA sequence comprising SEQ ID NO:2079.

Lai et al. characterize the year of 2003 is "heady times of miRNA gene discovery" (see page 16) and teach a computational, bioinformatics-based strategy of identifying miRNAs and miRNA precursor sequences, which is named "miRseeker", which incorporates an RNA folding algorithm. That is, they teach that a computational, bioinformatics-based approach based the structural features of known miRNAs combined with comparative genomics allows one to discover unknown miRNA gene "in a given sequenced genome". See page 16. They teach that their approach is based on the evolutionarily conserved stem-loop structure of miRNA precursors located in conserved genomic, non-coding sequences, sequence patterns, RNA folding, and folding energy, wherein the canonical miRNA precursor is about 70 to 100 nucleotides in length.

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They teach that they identified 48 novel miRNA candidates by using their computational “miRseeker” method, wherein 32 are newly verified. They teach that one can experimentally verify the computationally identified miRNAs by performing expression profile assays. They also teach that miRNAs can be identified by "direct cloning of mature 21-22 nucleotide RNAs, either from size-elected total RNA or from purified miRNP complexes." See page 15. See the entire reference including Figures 2-4 and Table 1.

Knipe et al. teach that HSV-1 genomic sequence is known in the art. See the entire reference.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the computational, bioinformatics-based “miRseeker” program of Lai et al. to discover miRNAs present in viral genome.

One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success, because Ambros taught that skilled artisans in the relevant art have recognized that miRNAs are widespread throughout different species of organisms and suggested that “many more miRNAs will be identified” in organisms that hadn’t been looked at, for example, those excluding worms, flies, and humans, by utilizing structure-based bioinformatics tools. As taught and suggested by Ambros, Lai et al. taught that many researchers have focused on finding more miRNAs as they call their research as "heady times of miRNA gene discovery". Further, concordant with the teachings of Ambros, Lai et al. actually demonstrated that one can screen and identify previously unknown miRNAs by utilizing computerized structure-based bioinformatics tools as long as the genomic sequence of interest is known. Since the genomic sequences of viruses were known and available including that of

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herpes simplex virus 1 (HSV-1) as taught by Knipe et al., and since the HSV-1 genomic sequence is "other" sequences than those of flies, worms, and humans, one of ordinary skill in the art would have been motivated to explore the HSV-1 genomic sequence by using the "miRseeker" program of Lai et al. in order to screen and discover miRNAs present in the HSV-1 genomic sequence. Since the "miRseeker" program of Lai et al. takes the length of the miRNA and the hairpin folding energy into account, the skilled artisan would have bioinformatically detected and obtained the claimed miRNA by running the miRNA screening/identification "miRseeker" program of Lai et al., wherein the miRNA is the sequence of SEQ ID NO:2079. Since all the tools, methodologies, knowledge, and resources required for the claimed invention were not only available but also within the technical grasp of one of ordinary skill in the art, and since "miRNA discovery" was an art-driven, art-recognized trend or goal, the claimed invention taken as a whole would have been *prima facie* obvious at the time of filing.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

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Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 21-22 and 25-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-8, 12 of copending Application No. 10/605,838. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant claims and the reference claims are directed to a genus of "viral" miRNAs.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 21-23, 25, 27-28, 33-34 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. to be determined

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(resulting from US Application No. 10/604,942). Although the conflicting claims are not identical, they are not patentably distinct from each other because the genus of miRNAs claimed in the instant case is anticipated by the species of miRNA claimed in the reference case.

Claims 21-23, 25, 27-28, 33-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 34-37 of copending Application No. 10/707,003. Although the conflicting claims are not identical, they are not patentably distinct from each other because the genus of miRNAs claimed in the instant case is anticipated by the species of miRNA claimed in the reference case.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 21-23, 25, 27-28, 33-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 23, 36, 39 of copending Application No. 10/604,943. Although the conflicting claims are not identical, they are not patentably distinct from each other because the genus of miRNAs claimed in the instant case is anticipated by the species of miRNA claimed in the reference case.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 21-23, 25, 30-34 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22, 34, 46 of copending

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Application No. 10/604,943. Although the conflicting claims are not identical, they are not patentably distinct from each other because the genus of miRNAs claimed in the instant case is anticipated by the species of miRNA claimed in the reference case.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DANA SHIN whose telephone number is (571)272-8008. The examiner can normally be reached on Monday through Friday, 7am-3:30pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James (Doug) Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Dana Shin
Examiner
Art Unit 1635

/J. E. Angell/
Primary Examiner, Art Unit 1635